



PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

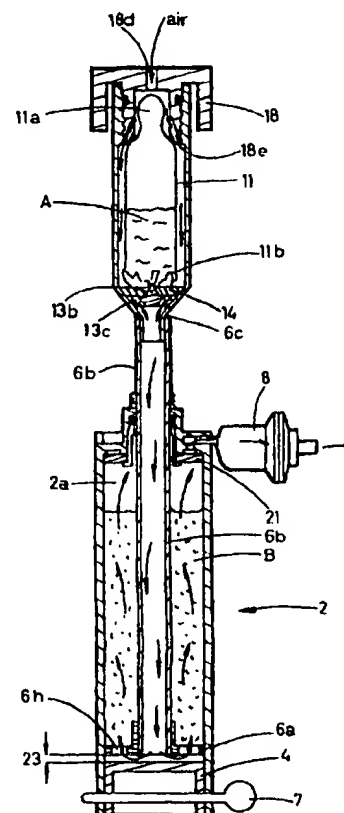
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁶ : B01F 3/12, 13/06, 15/02, A61F 2/46</p>	<p>A1</p>	<p>(11) International Publication Number: WO 97/18031</p> <p>(43) International Publication Date: 22 May 1997 (22.05.97)</p>		
<table style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <p>(21) International Application Number: PCT/SE96/01459</p> <p>(22) International Filing Date: 12 November 1996 (12.11.96)</p> <p>(30) Priority Data: <div style="display: flex; justify-content: space-between;"> <div>08/545,591</div> <div>13 November 1995 (13.11.95)</div> <div>US</div> </div> <div style="display: flex; justify-content: space-between;"> <div>08/734,817</div> <div>22 October 1996 (22.10.96)</div> <div>US</div> </div> </p> <p>(71) Applicant: CEMVAC SYSTEM AB [SE/SE]; P.O. Box 207, S-311 23 Falkenberg (SE).</p> <p>(72) Inventor: JONSSON, Sören; Rönnhagsvägen 38, S-589 41 Linköping (SE).</p> <p>(74) Agents: WILLQUIST, Bo et al.; Willquist & Partners Patentbyrå AB, S:t Larsgatan 23, S-582 24 Linköping (SE).</p> </td> <td style="width: 50%; vertical-align: top;"> <p>(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published With international search report.</p> </td> </tr> </table>			<p>(21) International Application Number: PCT/SE96/01459</p> <p>(22) International Filing Date: 12 November 1996 (12.11.96)</p> <p>(30) Priority Data: <div style="display: flex; justify-content: space-between;"> <div>08/545,591</div> <div>13 November 1995 (13.11.95)</div> <div>US</div> </div> <div style="display: flex; justify-content: space-between;"> <div>08/734,817</div> <div>22 October 1996 (22.10.96)</div> <div>US</div> </div> </p> <p>(71) Applicant: CEMVAC SYSTEM AB [SE/SE]; P.O. Box 207, S-311 23 Falkenberg (SE).</p> <p>(72) Inventor: JONSSON, Sören; Rönnhagsvägen 38, S-589 41 Linköping (SE).</p> <p>(74) Agents: WILLQUIST, Bo et al.; Willquist & Partners Patentbyrå AB, S:t Larsgatan 23, S-582 24 Linköping (SE).</p>	<p>(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published With international search report.</p>
<p>(21) International Application Number: PCT/SE96/01459</p> <p>(22) International Filing Date: 12 November 1996 (12.11.96)</p> <p>(30) Priority Data: <div style="display: flex; justify-content: space-between;"> <div>08/545,591</div> <div>13 November 1995 (13.11.95)</div> <div>US</div> </div> <div style="display: flex; justify-content: space-between;"> <div>08/734,817</div> <div>22 October 1996 (22.10.96)</div> <div>US</div> </div> </p> <p>(71) Applicant: CEMVAC SYSTEM AB [SE/SE]; P.O. Box 207, S-311 23 Falkenberg (SE).</p> <p>(72) Inventor: JONSSON, Sören; Rönnhagsvägen 38, S-589 41 Linköping (SE).</p> <p>(74) Agents: WILLQUIST, Bo et al.; Willquist & Partners Patentbyrå AB, S:t Larsgatan 23, S-582 24 Linköping (SE).</p>	<p>(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published With international search report.</p>			

(54) Title: METHOD AND DEVICE FOR FEEDING COMPONENTS FOR BONE CEMENT INTO A MIXING VESSEL FOR THESE

(57) Abstract

A method and an arrangement for successively feeding batches into a mixing vessel (2) under partial vacuum for the preparation of bone cement. The mixing vessel is pre-filled with a powder component (B) of said bone cement. A container containing a liquid bone cement (A) is connectable to the tubular rod (6b) of an agitator for mixing components (A, B) so that component (A) can be introduced into the mixing vessel by means of the vacuum present in said vessel. During mixing the agitator rod (6b) is sealed by a removable tightening rod. When mixing is completed tightening rod is removed from said tubular rod (6b) which now will serve as a spout for the bone cement. The bottom of the mixing vessel is movable and serves as a piston for emptying the mixing vessel through the spout.



Method and device for feeding components for bone cement into a mixing vessel for these

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to a method for successively feeding batches of constituent components into a mixing vessel for the preparation of bone cement under vacuum. The
5 invention also relates to an apparatus for successively feeding batches of constituent components into a mixing vessel under partial vacuum for the preparation of bone cement.

Description of the Prior Art

Bone cement is prepared by mixing polymethyl methacrylate in powder form, with liquid
10 monomethyl methacrylate in a mixing container. Both the liquid component and the combined mixture give off substances in gaseous form which are environmentally harmful and injurious to the health. For this reason, it is important for the introduction of the bone cement components into the mixing container and the mixing process itself, to take place in such a way that the smallest possible quantity of the harmful gases escape into the
15 surrounding environment. Mixing vessels in which the introduced components were successfully prepared into bone cement without a substantial release of the aforementioned gases are described in SE-C-8901599-4, SE-A0-9201353-1 and WO 94/26403, for example. In order for the bone cement to develop optimal strength during use, it is also important for the components comprising the cement to have well-mixed,
20 predetermined portions.

In said WO-publication a glass ampoule containing a liquid component of a bone cement is surrounded by a container which is in reclosable communication with the atmosphere. A second container surrounds the first container so that when the mixing vessel is opened,
25 the contents of the ampoule, under the effect of a partial vacuum inside the mixing vessel, can be sucked down into it, a space formed between the aforementioned inner container and outer container is filled with a second bone cement component in powder form which is caused by displacement of the inner container relative to the outer container, to move from a first position in which the space does not communicate with the atmosphere or the
30 mixing vessel to a second position in which the space communicates with the atmosphere

and the mixing vessel, so that the powdered bone cement component is sucked down into the mixing vessel under the effect of the partial vacuum inside it.

A device for carrying out the above method which device is also explained in said WO-
5 publication is characterized in that it comprises, an inner container communicating with the atmosphere, and is so arranged as to enclose the glass ampoule containing the liquid bone cement component, and to communicate with the aforementioned mixing vessel, and which includes means for opening the ampoule so that its contents, under the effect of the partial vacuum inside the mixing vessel, can be sucked down into it. The outer container at
10 least partially encloses the inner container and is also arranged so as to communicate with the mixing vessel and together with the inner container, defines a space therebetween which is filled with a certain quantity of the powdered component of bone cement. The inner container is capable of displacement from a first position to a second position, the first position characterized by the inner container preventing communication between both
15 the mixing vessel and the atmosphere, and the second position characterized, in which communication between the mixing vessel on the one hand and the atmosphere on the other hand is open, so that the bone cement component in powder form, under the effect of the partial vacuum inside the mixing vessel, can be sucked into it without escape of gases.

20 SUMMARY OF THE INVENTION

One object of the present invention is to make available a method and device of the kind described above, which avoids the risk of gas release when feeding the bone cement components into the mixing vessel. Another object is to make the mixing as convenient
25 and simple as possible for a person using the device. Still another object is to make the mixing as safe as possible for said person i.e. reduce to a minimum the failure rate of mixing. This is achieved in accordance with the invention in a number of ways. According to one method, which has a couple of variants, the outer or second container is eliminated and the mixing vessel is prefilled with the powder bone cement component. The first
30 container holding the ampoule of the liquid bone cement component connects to the mixing vessel in a manner where displacement of a container cap causes the liquid components to be sucked into the mixing vessel under vacuum.

According to another method, the first and second containers are eliminated and the liquid bone cement components is supplied through a collapsible plastic bag and tubing arrangement attached thereto. The tubing can be connected to the mixing vessel in at least two convenient locations, where a tubing clamp is released to allow the liquid component
5 to flow into the mixing vessel under the influence of vacuum.

Along the same lines of eliminating the first and second containers, another method of the present invention simply involves a providing a glass ampoule with the liquid component therein, breaking the ampoule, and then supplying the contents into the mixing vessel
10 through a funnel attached thereto. Again the liquid component is sucked under vacuum into the mixing vessel.

A final method of the present invention again involves use of a first container for holding an ampoule, but now the container is melded to the mixing tube for directly draining into
15 the bottom of the mixing vessel.

The devices for carrying out all methods in accordance with this invention are more fully detailed in the following sections.

20 BRIEF DESCRIPTION OF THE DRAWINGS

The invention is described below in greater detail with reference to the accompanying drawing, in which:

Figure 1 illustrates the mixing vessel of a first embodiment of the present invention in
25 which the powder form of the bone cement pre-exists within the mixing vessel;

Figure 2 illustrates a container and a cassette that houses a glass ampoule which contains the liquid form of the bone cement;

Figure 3 illustrates a cross-sectional view of the mixing vessel of Figure 1 prior to mixing the cement components;

30 Figure 4 illustrates the mixing vessel of figure 3, feeding the liquid into the vessel;

Figure 5 illustrates the mixing vessel of Figure 1 with the bone cement components thoroughly mixed;

Figure 6 illustrates the mixing vessel of a second embodiment of the present invention in which the liquid form of the bone cement is fed into the mixing vessel through the side wall;

Figure 7 illustrates the mixing vessel of a third embodiment of the present invention where the liquid bone cement component is contained in a collapsible plastic bag.

Figure 8 illustrates a fourth embodiment of the present invention, which is a variant to the Figure 7 embodiment;

Figure 9 illustrates the mixing vessel of an fifth embodiment of the present invention where the liquid form of the bone cement component is contained in a separate container and feed through a funnel to admix with the powder bone cement component.

Figures 10a and 10b illustrates the mixing vessel of a sixth embodiment of the present invention where the liquid cement container is inserted inside the tubular rod and joined thereto and the bone cement components are mixed.

15 DETAILED DESCRIPTION OF THE INVENTION

The designations 1 and 2 are used generally in the drawing in respect of a feed arrangement and a mixing vessel. The latter comprises an interior 2a, a cylindrical container 3 comprised of an outer cylinder wall 3a, a bottom 4 at one end of the container and a spout 5 with sealed opening at the other end, together with an agitator 6, received within said spout and mixing vessel and capable of axial, vertical movement inside the container 3. The agitator 6 consists of an agitator disc 6a attached to a tubular agitator rod 6b. The agitator 6 is mounted so that it is free to vertically slide up and down while maintaining a seal in the spout 5, in such a way that the plurality of holes 6h in agitator disc 6a can be used to bring about through mixing of the bone cement components A, B within mixing vessel 2 with no gaseous escape to atmosphere. Once mixing is complete, and once a lock 7 has been removed, the bottom 4 can be axially displaced inside the cylinder by upward movement of piston head 80, moving towards the spout 5. The piston-like function of bottom 4, upwardly pushes and then discharges the mixed bone cement via the hollow agitator rod 6b, which now serves as a discharge nozzle. The interior of the container 2 communicates via a filter 8 with a vacuum source (not shown) during feeding and mixing of the bone cement components A, B. Rapid and effective feeding of the bone

cement components A, B into the mixing vessel, and safe handling of the gases that are environmentally harmful and injurious to human health, are achieved in this way.

Turning attention now to Figures 1-6, a first and a second embodiment of the present invention will now be described. The powdered component B of bone cement pre-exists within the mixing vessel 2 prior to any mixing procedures, and the container 9 contains only the liquid component A. It will become clearer after reading the following description that the main characteristic of the first embodiment is that the liquid component A will be drawn into the mixing vessel under vacuum, and that an ampoule arrangement is provided wherein the ampoule rests on the mixing vessel and wherein the contents feed downward through the tubular agitator rod 6b, and enter vessel 2 in the vicinity of the vessel bottom 4. The second embodiment uses a similar ampoule arrangement, however, the ampoule does not rest on the mixing vessel and the contents enter through the outer cylindrical wall 3a, also near the mixing chamber bottom 4. The first and second embodiments, as well as the third one described later, are also provided with a second filter 21, located at the top of mixing vessel 2.

In accordance with the first embodiment, Figures 1-5 show mixing vessel 2 as being pre-filled with the powder component B of the bone cement. A tightening rod 19 is received within tubular agitator rod 6b of agitator 6 and has plug 19a and O-ring 19c inserted within a groove 19b thereof, to form an air-tight seal so that powdered contents B are not contacted by and affected by atmospheric air which is capable of downwardly travelling along tubular rod 6b to vessel bottom 4. Just prior to introducing glass ampoule 11 on top of mixing vessel 2, tightening rod 19 is completely removed from tube 6b, wherein the cylindrical container 9 is placed on top of vessel 2 by inserting funnel-shaped neck 9c into mouth 6c at the first end 6d of tubular rod 6b. Figure 2 shows in greater detail that glass ampoule tip 11a is pointing upwards when inserted within container 9, and that the ampoule is resting upon the upward cone 13b of breaking means 13, said means having internal passages 13c for allowing liquid there through once it passes filter 14. Figure 2 also illustrates that cap 18 has gripping means 18h for facilitating the operative threading movement of cap 18 along container threads 12a. Figure 3 shows the ampoule 11 just prior to being broken. Figure 4 shows that when handle 18h of the cap is turned so as to

downwardly displace the cap 18 through action of the interacting threads 12a and 18a, shoulder 18s pushed downwardly against ampoule 11, causing upward-facing, pointed cone 13b to break bottom 11b of the ampoule, thereby allowing liquid contents A to flow through filter 14 under suction downwardly into hollow tube 6b as previously described.

5 As Figure 4 shows, openings 18d and 18e in cap 18, allow atmospheric air to be communicated into the interior of container 9 under suction, also as previously described, thereby preventing noxious fumes escaping to atmosphere. A small gap 23 exists between vessel bottom 4 and agitator disk 6a so that as liquid A descends tubular rod 6b, exists open end 6e, then it enters gap 23, which behaves as a passage for percolating an air/liquid
10 mixture upwardly through holes 6h in the agitator disk 6a, so that air bubbles cause liquid A to thoroughly mix with the powder component B, while under the continuing action of the vacuum source. Figure 5 illustrates that once ampoule 11 is empty, container 9 is removed and replaced with tightening rod 19. While still under vacuum, tubular rod 6b is grasped and then successively moved up and down in the direction of arrow 30 and down
15 with rod 19 still inserted therein, as the outlined representation in Figure 5, so that agitator disk 6a ensures thorough mixing of the liquid and powder components A, B, while rod 19 prevents gaseous escape from tubular rod 6b due to O-ring seal 19c. The filter 21 is provided to prevent heavy particulate from being drawn into the vacuum source not shown. Once admixed, first lock 7 and then rod 19 are removed and bottom 4 can be
20 axially displaced within cylinder 3 in a fashion similar to a piston, as previously described, so that the mixed bone cement can be pushed out of vessel 2 once tightening rod 19 is removed. In this way, agitator rod 6 is pulled completely up so that agitator disk 6a contacts the top end 3b of cylinder 3, with tubular rod 6b acting as a discharge nozzle for the now-ready cement.

25

Figure 6 shows a second embodiment of the present invention wherein the mixing vessel is again pre-filled with powder component B and where container 9 has top end 9a connected to a tube 26, shown as being inserted into hole 27 which penetrates cylinder wall 3a. It is to be understood that prior to insertion of tube 26, plug 121 is inserted within
30 hole 27, thereby maintaining a seal from the atmosphere. When mixing is to take place the interior of the mixing vessel 2 is put under vacuum by starting the vacuum source, not shown. Then plug 121 is removed, tube 26 is inserted into hole 27 and the glass ampoule

containing liquid A is broken. By percolation of air and liquid A through powder component B in mixing vessel 2 a pre-mixing is obtained. When the ampoule is emptied tube 26 is removed from hole 27, plug 121 is inserted and final mixing by means of the agitator is performed, as previously described in connection to Figure 4. After finished
5 mixing lock 7 is removed and the contents pushed upwards with piston head 80 for eventual discharge out tube 6b.

Figure 7 shows a third embodiment, where container 9 is now comprised of collapsible plastic bag. This substitution advantageously reduces the cost to manufacture, and is less
10 bothersome than breaking and discarding the glass ampoule bottles. Again, this arrangement functionally mixes the elements together as previously explained. However, as seen in Figure 7, a U-shaped sleeve member 29 is used as a valve, where tube 26 is folded and frictionally inserted within sleeve interior 29a, thereby blocking any flow of material A. Then, plug 121 is removed from cylinder wall 3a, and is inserted into hole 27.
15 Figure 7 shows a coupling 30 being inserted into tube 26 to facilitate the connection into the cylinder wall to allow discharge of liquid A into mixing vessel 2. It should be realized that the embodiments of Figures 1-6 could also be provided with coupling 30 if desired. Mixing is completed by upwardly and downwardly moving agitator disk 6a as previously described, using mouth 6c of rod 6b as a discharge nozzle once disk 6a is contacted
20 against top end 3a of cylinder 3, and tightening rod 19 is removed so that the mixed contents can be pushed upwards by bottom 4.

Figure 8 shows a fourth embodiment of the present invention where it is seen that the means for introducing the liquid into the mixing vessel is now in the form of a collapsible
25 bag of Figure 7 is directly inserted into tubular agitator 6b once tightening rod 19 is removed, as is shown. Then, the U-shaped sleeve member 29 is removed from tube 26 so that liquid component A is drawn under the influence of vacuum down to the bottom of tubular agitator rod 6b, and be mixed as previously described. An airtight adapter means 42 is provided at the tube end so as to securely hold it within tube 26 during introduction
30 of the liquid A.

Figure 9 shows a fifth embodiment of the present invention where it is seen that the cylindrical containers 9 and 10 are eliminated so that once the glass ampoule 11 is broken, the liquid bone cement component A, is introduced into mixing vessel 2 via removable funnel member 50 and hollow agitator rod 6b. As seen open funnel neck 52 is in frictional engagement with the open mouth 6b' of rod 6b when funnel 50 is inserted therein. The tip 11a of ampoule 11 is broken off and contents A are fed into funnel component receiving area 50a before descending down tube 6b. Again, this arrangement provides the liquid component A at the container bottom so that both components A, B can be pre-mixed together through percolation as previously explained. However, since there is no longer an enclosure for sealing the ampoule once it is broken, in order to prevent atmospheric releases prior to mixing, the suction pressure on vacuum source may be increased over that of the previous embodiments. High velocity of ambient air entering into the funnel 50 will prevent fumes from escaping from mixing vessel 2 out into the operating theatre. It is envisioned that funnel member 50 be provided with an O-ring or similar seal about its open neck 52.

Figures 10a and 10b show a final embodiment of the present invention, where it is seen that the container 9 and cap 18 as presented in Figures 3 and 4, is provided in Figures 10a and 10b in a slightly modified fashion, where the glass ampoule 11 is now resting on breaking means 13 and that filter 14 is disposed below the breaking means. Furthermore, the container 9 is formed with a neck 9c that either inserts inside tubular rod 6b or as shown here, is formed so that rod 6b inserts inside neck 9c. In either case, once the connection is made, the neck and the tube are joined together by known methods of friction spin-melting the like elastomeric components together, or they can be joined by conventional methods such as gluing, threading, or snap-fitting the pieces airtight to each other. Once connected, the cap 18 gripping means 18h are operatively threaded downward along container threads 12a, until shoulders 18s cause the glass ampoule to be broken against pointed cone 13b of the breaking means. The liquid component A passes from container 9, downwardly through filter 14, now located in neck 9c, then into hollow tubular member 6b, before passing through a second filter 14b at tube open end 6e. Ambient air is as previous drawn together with the liquid A into the vessel thereby preventing fume to escape to the outside of the container. The liquid A then changes

direction at the bottom of mixing vessel 2 due to the action of vacuum from vacuum source not shown and turns upwardly to percolate into the powdered bone cement component B (premixing as previously described). Plug 18p is then inserted into opening 18d to seal container 9 from atmospheric influence. The container 9 is gripped as a handle
5 and stroked up and down, thereby causing agitator disk 6a to mix the two bone cement components A, B together, as previously explained with the other embodiments. As Figures 10a and 10b show, tubular element 6b is scored with an annular notch 6s, that allows the container-tubular rod to be separated from each other by snapping the container in a perpendicular direction to the rod, thereby breaking the rod at the notch. This step is
10 performed after mixing is complete and after the tubular rod and agitator stick have been pulled back towards piston 80. Once the tubular element 6b is pulled back, mixing vessel 2 is turned upside down in order to facilitate removal of the mixed bone cement. A comparison of Figures 10a and 10b to Figure 3 makes this point more clear in that mixing vessel 2 in Figures 10a and 10b is initially upside down such that spout 5 is sealed with a
15 removable closure 5a and where the cylindrical container outer wall 3a also acts as the mixing vessel bottom, wherein the agitator 6 is inserted through the bottom of the container 3, rather than through the spout 5, as with the previous embodiments. With this arrangement, once the mixing is completed and the rod fractured at notch 6s, pin 7 is removed, as is filter 8 to vacuum source, so that piston 80 is advanced into contact with
20 the bone cement mixture in the same manner as previously described with the other embodiments, and the mixture is pushed out of mixing vessel 2 through spout 5, of course once closure 5a is unthreaded and removed. A filter resting against the piston 80 prevents cement from entering into the vacuum source and will likewise prevent cement from leaking out through the piston when this is advanced into contact with the cement. Spoute
25 5 is used for attaching of various extrusion nozzles.

Patent Claims

1. An apparatus for successively feeding batches of a liquid and a powder component (A, B) into an interior of a mixing vessel (2) for the preparation of a bone cement, said mixing vessel (2) interior (2a) maintained under a vacuum created from a vacuum source in order to prevent harmful emissions from escaping from said vessel once said liquid and powder components (A, B) are mixed, comprising:
5 a mixing vessel (2) pre-filled with a powder component (B) of said bone cement, said vessel (2) defined by an outer wall (3) having a top end, a bottom end and an interior, said top end formed with a sealable spout (5), said bottom end formed with an axially displaceable bottom (4);
10 a means (1) for introducing said liquid component (A) into said interior of said mixing vessel (2) through said sealable spout (5);
an agitator (6) received within said vessel interior (2a), said agitator (6) comprised of a tubular rod (6b) which extends upwardly out of said interior through said spout (5) and is in communication with the atmosphere and an agitator disk (6a)
15 attached to said tubular rod (6b), an open, first end of said tubular rod defining a mouth and an open, second end of said tubular rod encircled by said disk (6a), said tubular rod (6b) axially displaceable within said vessel (2) interior for mixing said bone cement components (A, B);
a removable tightening rod (19) disposed within said tubular rod (6b) for sealing
20 said open bottom rod end from communication with the atmosphere after said liquid component (A) is introduced into said mixing vessel (2), said tightening rod (19) being disposed within said tubular rod (6b) prior to introducing said liquid (A) into said mixing vessel (2);
wherein said tightening rod (19) is removed from said tubular rod (6b)
25 immediately prior to introducing said liquid bone cement (A) compound into said mixing vessel (2) and is reinserted therein after said liquid (A) is introduced within said mixing vessel, wherein said powder (B) and liquid (A) components are then mixed within said vessel (2) interior (2a) under a continuous vacuum from said vacuum source and said atmospheric air is prevented from entering into said vessel

(2) due to said tightening rod (19), wherein said harmful emissions caused from mixing said components (A, B) are prevented from escaping said vessel (2).

2. The apparatus of Claim 1 wherein said means (1) for introducing said liquid (A) into said vessel (2) is comprised of a container (9) having an interior for containing said liquid (A), a tip (11a) and a tube (26) connected to said tip, said tube connecting said container to said mixing vessel (2).
3. The apparatus of Claim 2 wherein said tube (26) has a one end of said container inserted into said open top end of said tubular rod (6b).
4. The apparatus of Claim 2 wherein said tube (26) has a one end inserted into said outer wall (3) of said mixing vessel (2), near said bottom end.
5. The apparatus of Claim 2 wherein said tip of said container is inserted into a funnel (50), said funnel (50) having an open neck that is removably inserted into said open end of said tubular rod (6b).
6. The apparatus of Claim 2 wherein said plastic tube (26) is provided with a clip (29) for opening and closing said tube (26) upon demand.
7. The apparatus of Claim 5 wherein said container is comprised of one of a glass and plastic ampoule.
8. The apparatus of Claim 5 wherein said container is comprised of a collapsible plastic bag.
9. An apparatus for successively feeding batches of a liquid and a powder component (A, B) into an interior of a mixing vessel (2) for preparation of a bone cement, said mixing vessel (2) interior (2a) maintained under a vacuum created from a vacuum source in order to prevent harmful emissions from escaping from said vessel (2) once said liquid and powder components (A, B) are mixed, comprising:

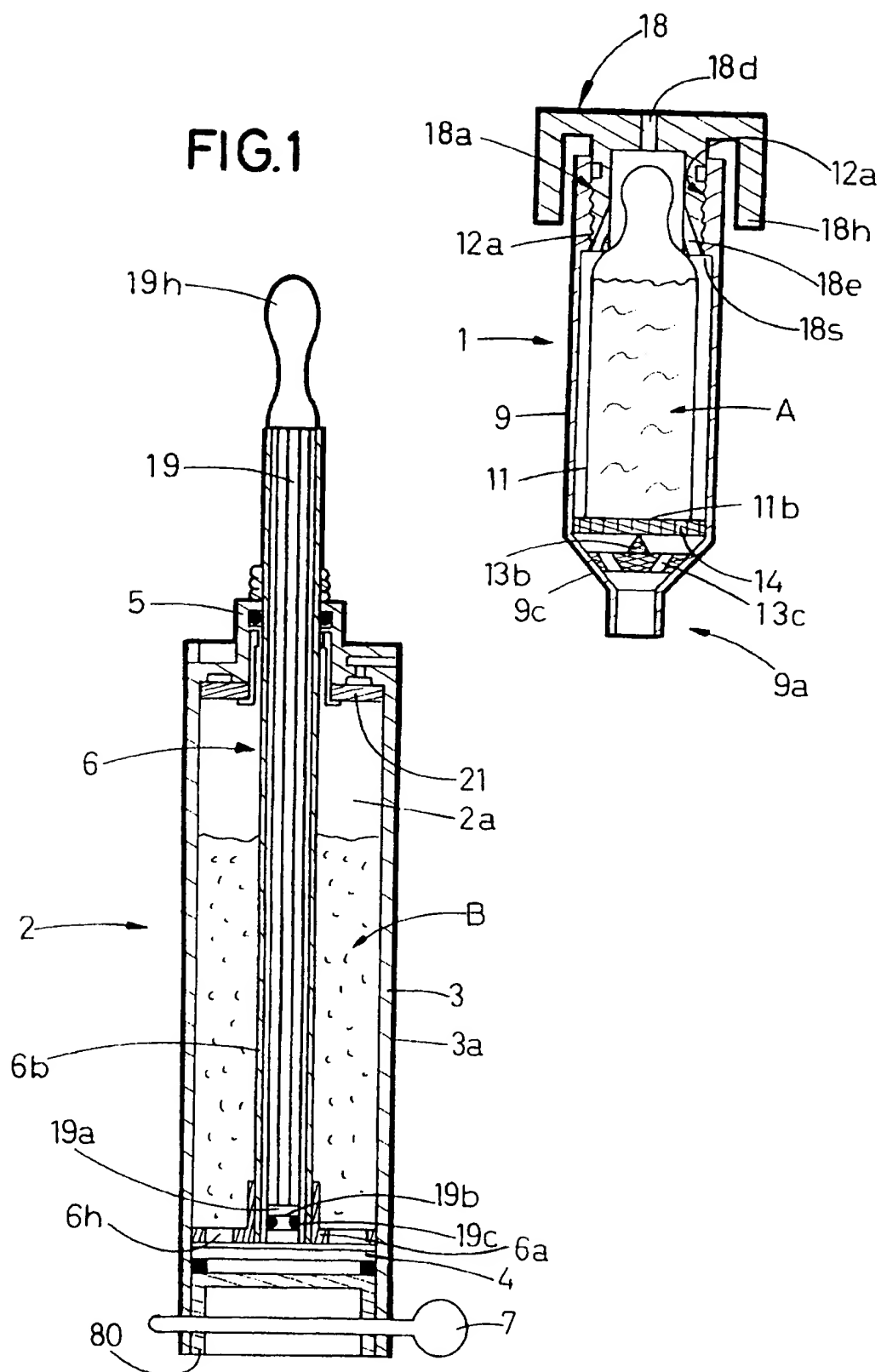
- a mixing vessel (2) pre-filled with a powder component (B) of said bone cement, said vessel (2) defined by an outer wall (3) having a first end, a second end and an interior (2a), one of said first and second ends formed with a sealable spout (5), the other of said first and second ends formed with an axially displaceable bottom (80), said bottom having a central opening therein;
- 5 an agitator (6) received within said vessel interior (2a), said agitator (6) comprised of a tubular rod (6b) which extends upwardly out of said interior through said opening in said bottom (80) and an agitator disk (6b) attached to said tubular rod, said tubular rod (6b) having an open, first end that defines a mouth and an open,
- 10 second end that is encircled by said disk, said tubular rod (6b) axially displaceable within said vessel interior for mixing said bone cement components (A, B);
- a means for holding and introducing said liquid component (A) into said interior of said mixing vessel (2);
- wherein said means for holding and introducing is joined to said mouth of said
- 15 tubular rod prior to feeding said liquid contents (A) into said vessel (2) through said tubular rod (6b), wherein said powder and liquid components (B, A) are mixed within said vessel interior (2a) under a continuous vacuum so that said harmful emissions caused from mixing are prevented from escaping said vessel (2), and wherein said mixed bone cement component (A, B) is pushed out of said
- 20 sealable spout (5) through a displacement of said vessel bottom (80).
10. The apparatus of Claim 9 wherein said means for holding and introducing said liquid component (A) is operatively connected to the agitator rod (6b) in order to be used as a handle during mixing.
- 25 11. The apparatus of Claim 9 wherein said means for holding and introducing said liquid component (A) is comprised of a generally cylindrical container that is defined by a top, a bottom and an interior, said bottom having an opening therein which is in communication with said mouth of said tubular rod (6b), said top
- 30 having a removably threaded cap (18) thereon for engagement with an ampoule (11) containing said liquid (A), said ampoule received within said container interior and resting on a means (13b) for breaking said ampoule, said breaking

means (13b) anchored to said container interior above said opening in said container bottom, said cap having a reclosable opening (18d) therein and a pair of shoulders (18s) in contact with said ampoule, said shoulders (18s) for pushing said ampoule (11) against said breaking means (13b) through a downward threading of said cap (18), thereby breaking said ampoule (11) so that said liquid (A) is introduced into said tubular rod (6b) and into said mixing vessel (2).

12. A method for successively feeding in an arbitrary sequence batches of a liquid and a powder bone cement component (A, B) into a mixing vessel (2) maintained under vacuum for the preparation of said bone cement wherein said mixing vessel (2) is provided with a pre-determined amount of said powder component (B) of said cement, the method comprising the steps of providing a mixing vessel (2) which said vessel is defined by a cylindrical cylinder having an open interior (2a) with a spout attached to one end of said cylinder, and having an axially displaceable bottom (4);
- inserting a mixing agitator (6) within said spout so as to communicate with said vessel interior (2a), said agitator (6) comprised of a tubular rod (6b) having an agitator disk (6a) fixed on one end thereof, said other end being open and defining a mouth, said mouth being located axially above said spout of said vessel, said agitator (6) axially displaceable such that said agitator disk (6a) can mix both of said bone cement components (A, B) together;
- providing a tightening rod (19) within said tubular rod (6b) so as to seal said vessel (2a) from said atmosphere before said liquid component (A) is introduced into said vessel (2a);
- removing said tightening rod (19) and then introducing said liquid component (A) into said interior of said vessel (2a) near said vessel bottom (4);
- re-inserting said sealing rod (19) within said tubular rod, thereby sealing said vessel (2a) from said atmosphere;
- axially displacing said agitator (6) so as to mix said liquid and powder components (A, B) under vacuum, without allowing harmful emissions to escape said mixing vessel.

13. The method of Claim 12, wherein said container providing a container which has an open interior for receiving a glass ampoule (11) and a threadable cap (18) for pushing downwards on said ampoule, said interior including a means (13a) for breaking said ampoule (11) when said cap (18) pushes on said ampoule (11) thereby allowing said container to feed liquid (A) into said vessel (2).
14. The method of Claim 12 further comprising the step of placing said container in said mouth of said tubular rod (6b), and operatively connecting container (9) and rod (6b) for using the container (9) as a handle during mixing.
15. The method of Claim 12 further comprising the step of providing a hole in said container (9) wall and connecting a tube between said container (9) and vessel (2) in order to feed said liquid (A) through said tube to said container bottom.
16. The method of Claim 12 wherein said container (9) is a plastic bag containing said liquid (A) and said container (9) is provided with a tube that connects said container with the vessel wall in order to feed said liquid (A) into said vessel (2) at said bottom.

FIG. 2



2/10

FIG. 3

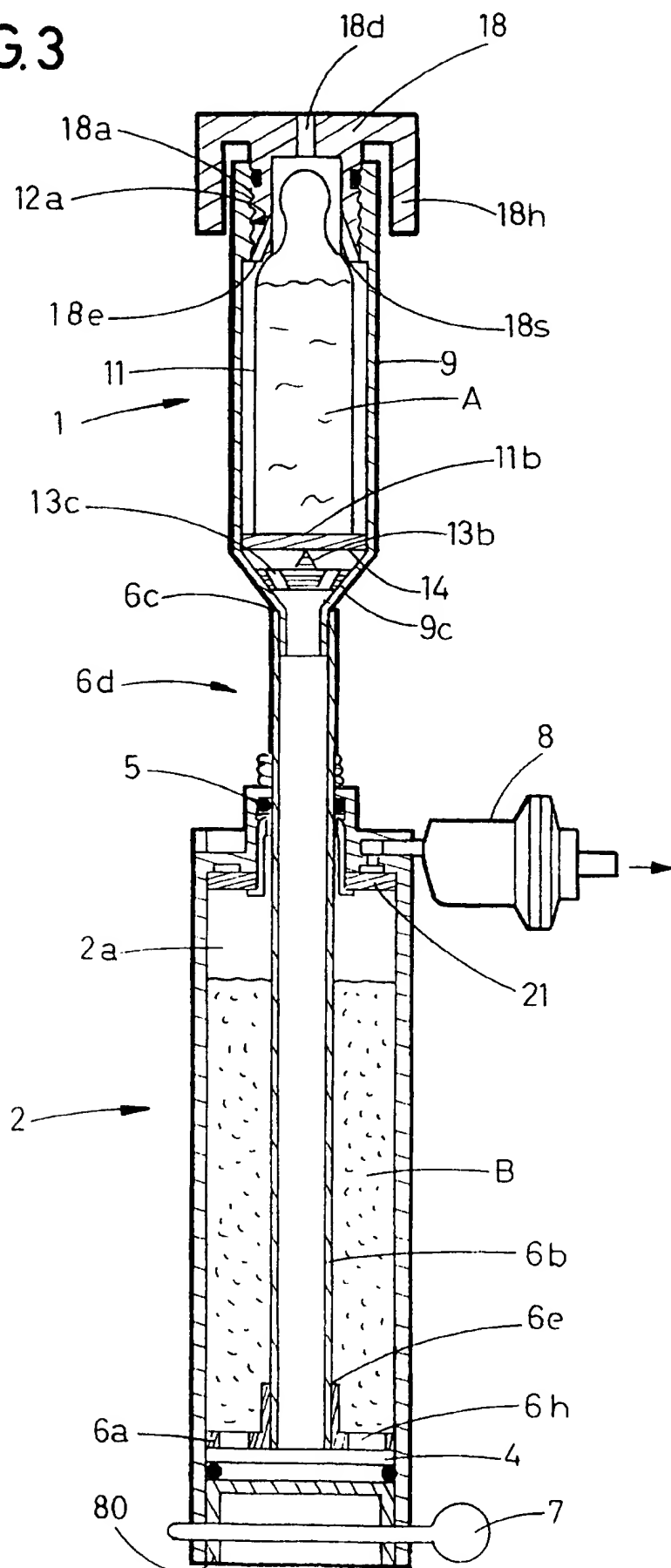


FIG.4

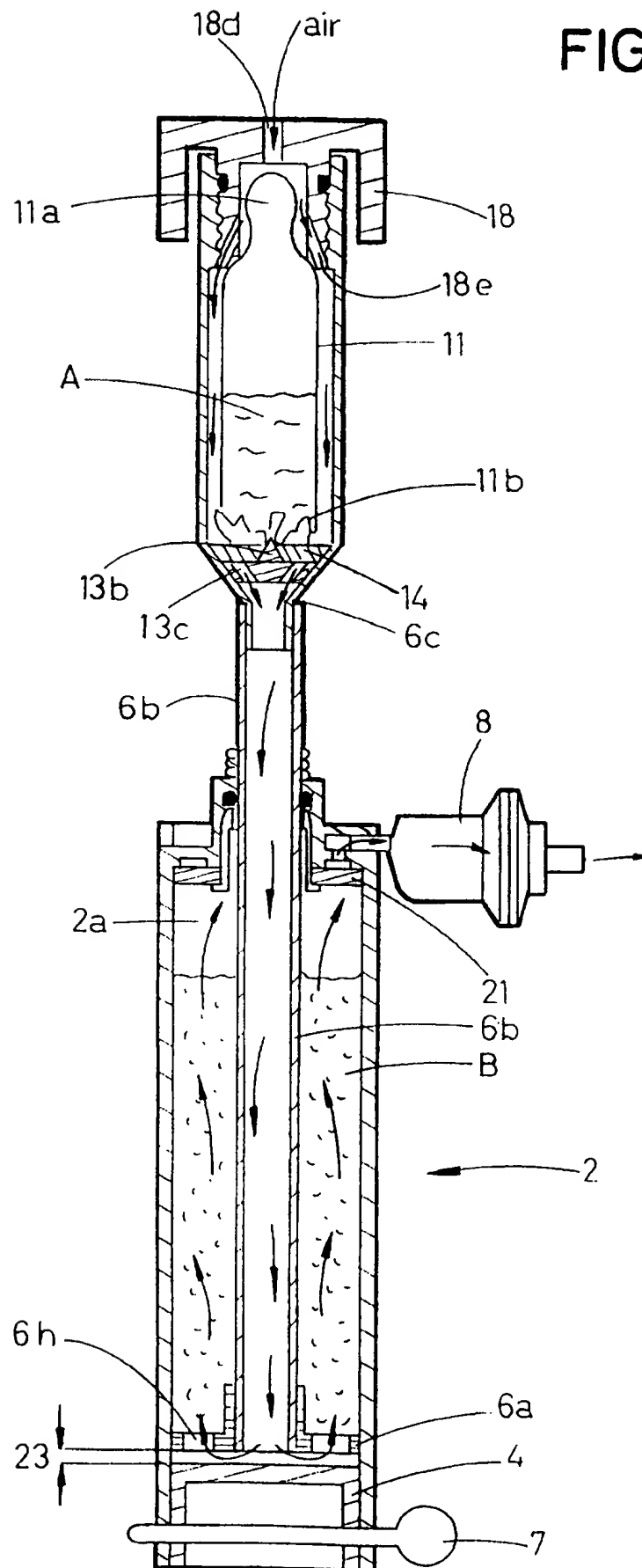


FIG. 5

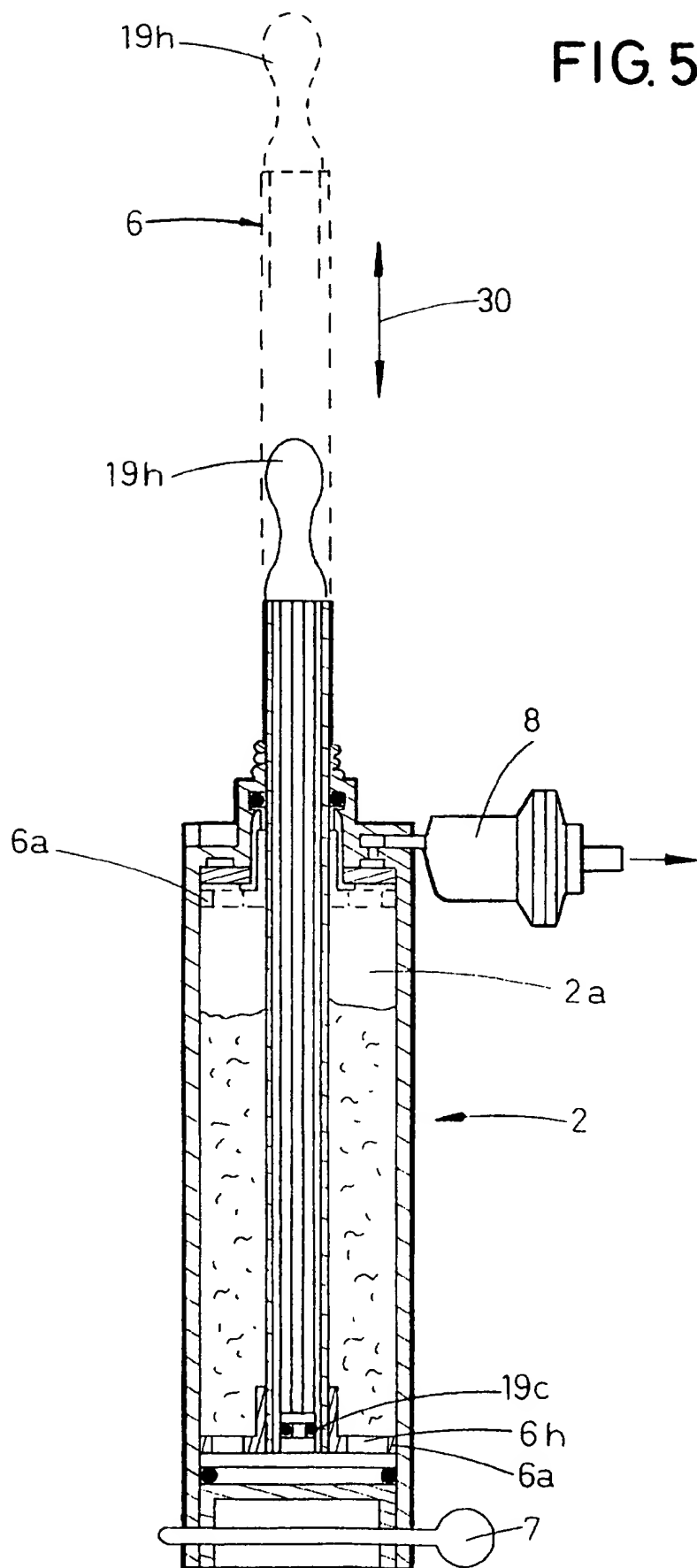


FIG. 6

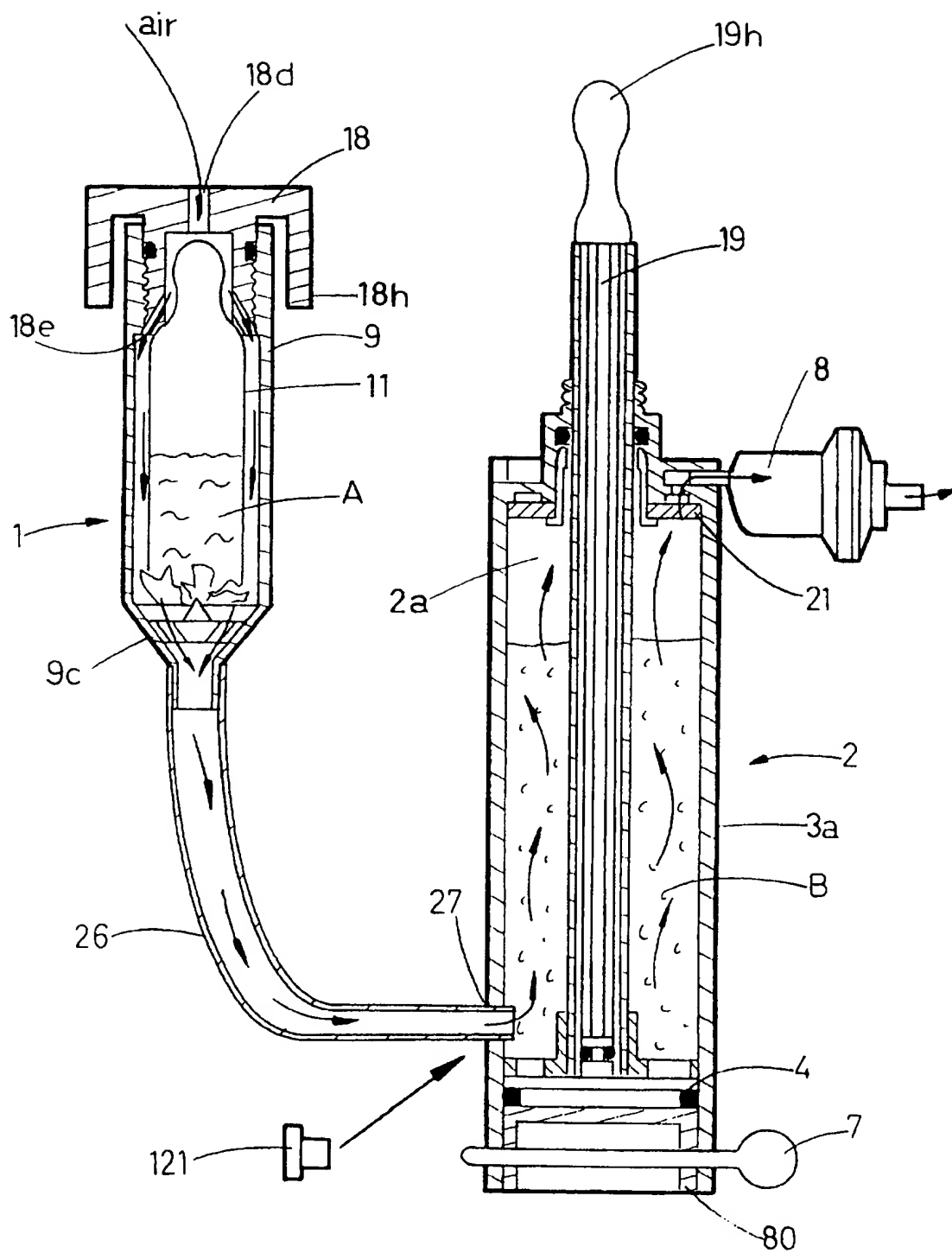


FIG. 7

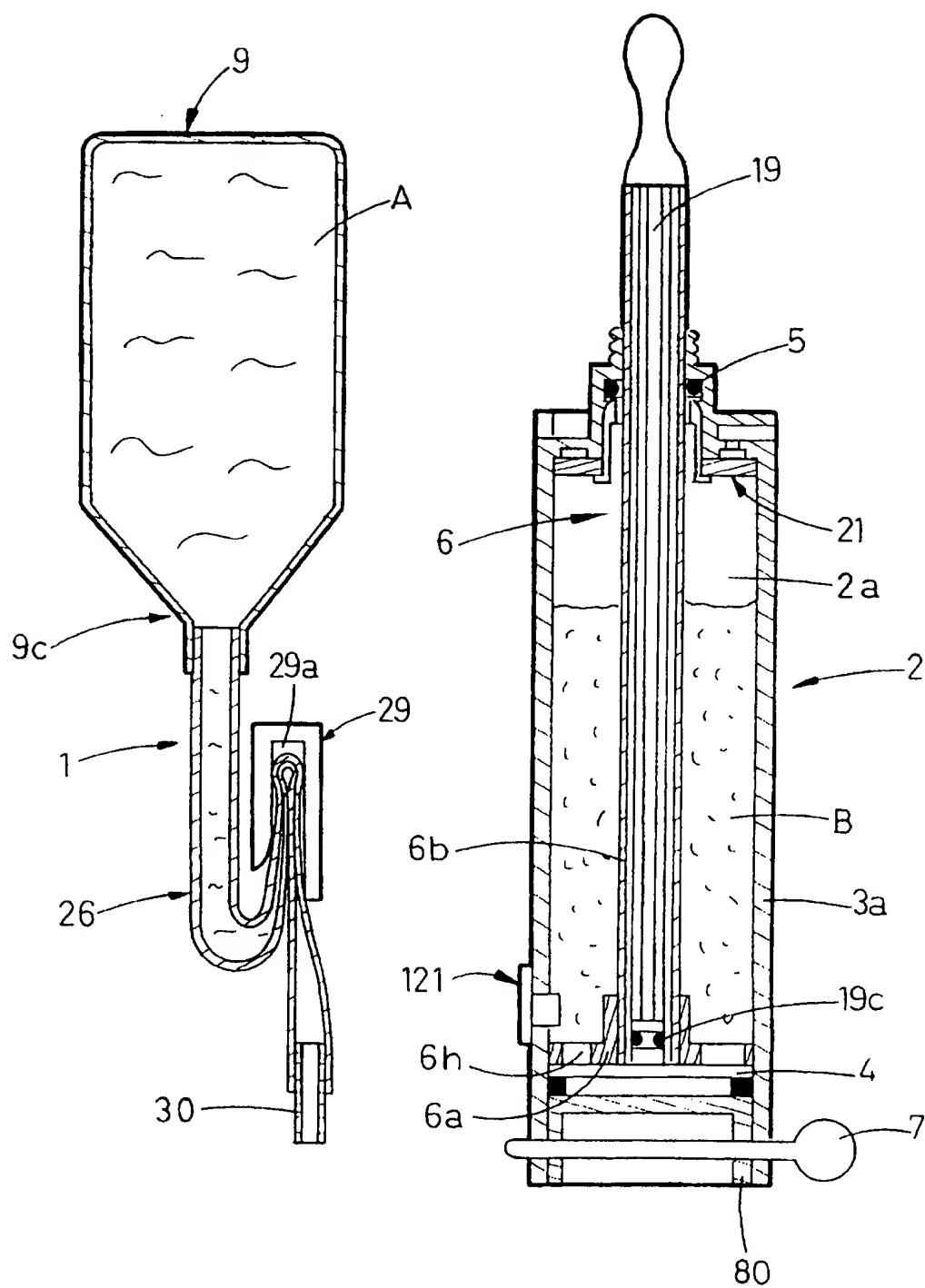


FIG. 8

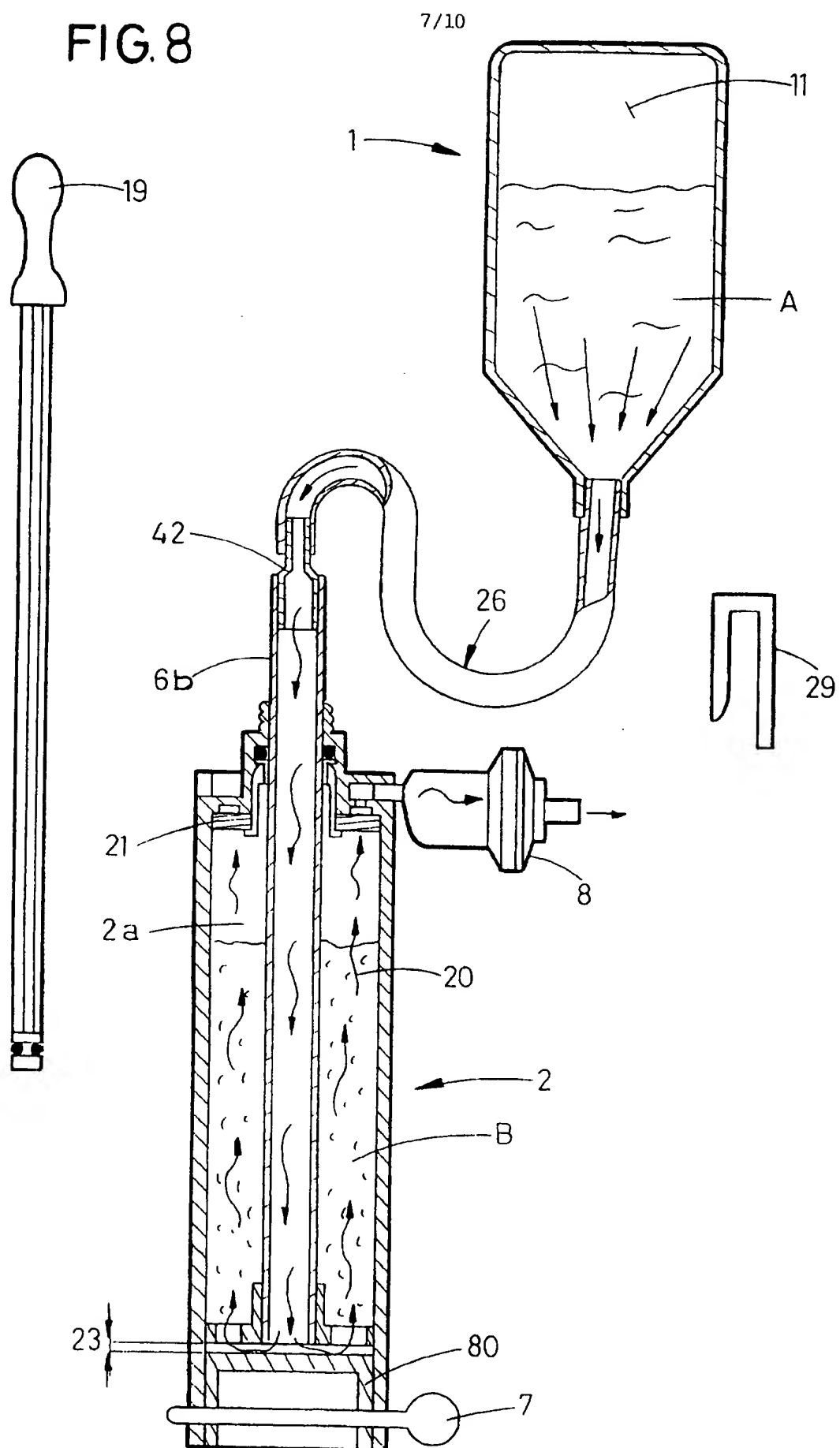


FIG.9

8/10

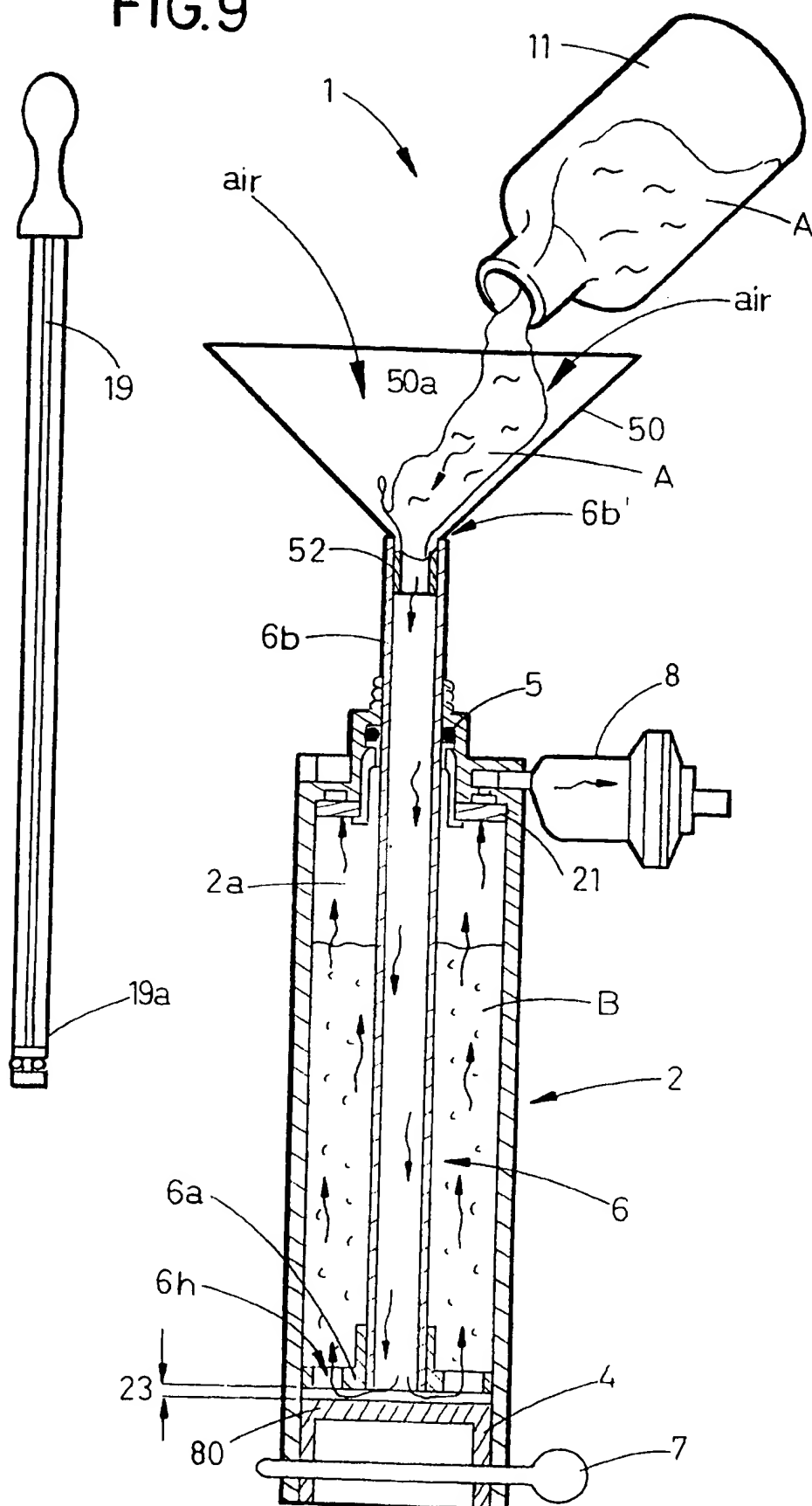


FIG.10a

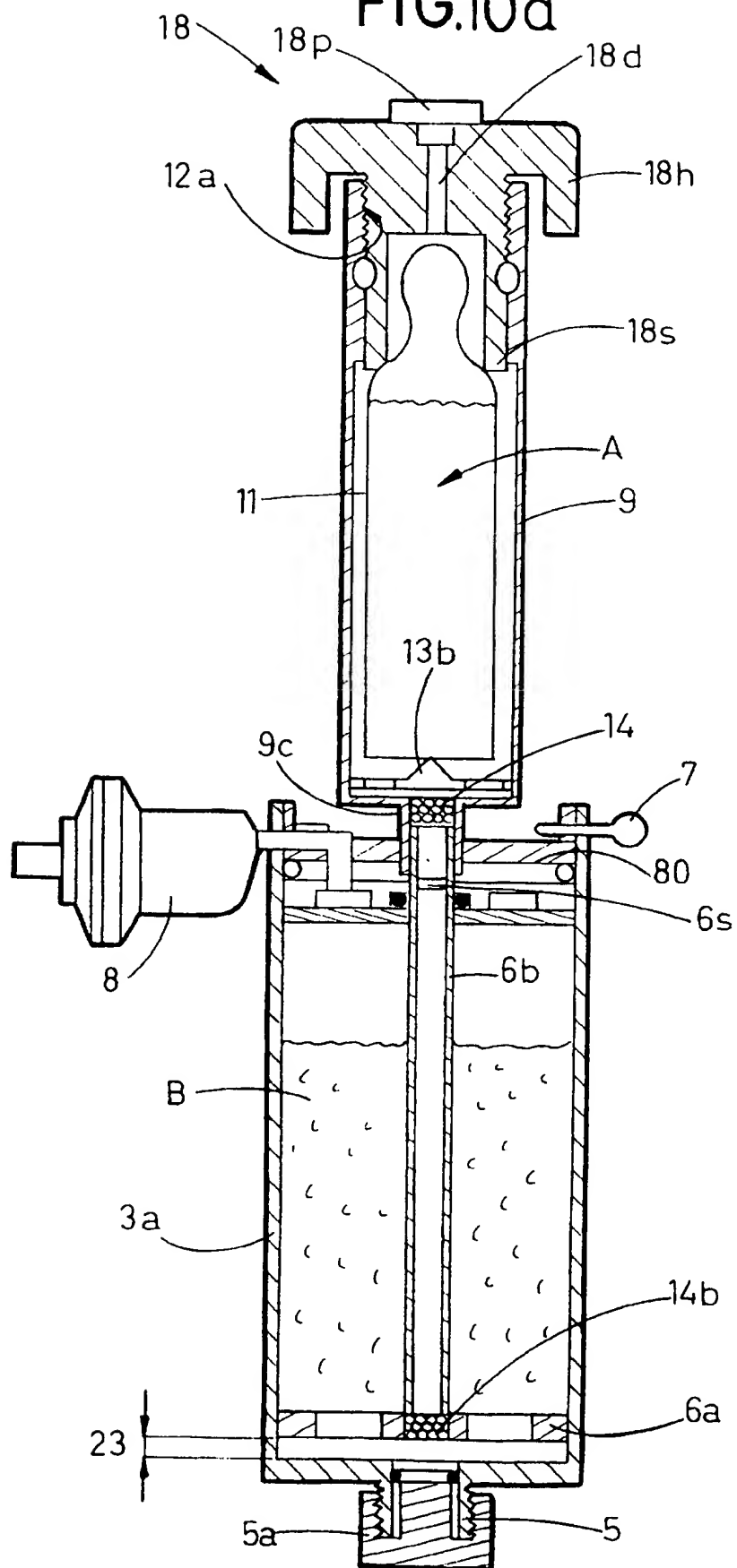
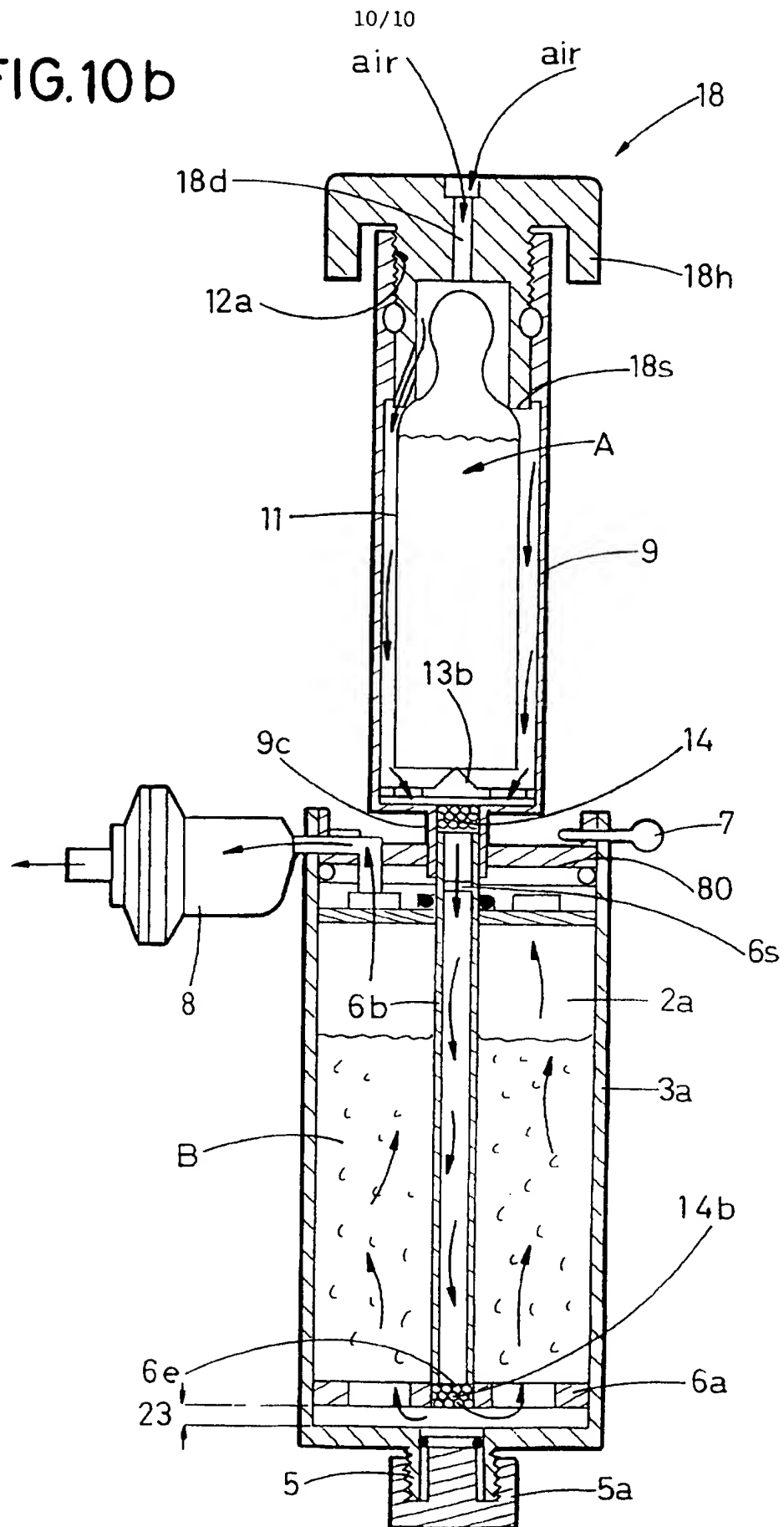


FIG.10b



INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 96/01459

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: B01F 3/12, B01F 13/06, B01F 15/02, A61F 2/46
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: B01F, A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 9426403 A1 (CEMVAC SYSTEM AB), 24 November 1994 (24.11.94), figures 1,4, abstract --	1-16
A	WO 9322041 A1 (CEMVAC SYSTEM AB), 11 November 1993 (11.11.93), figures 1,5, abstract -- -----	1-16

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
 "E" earlier document but published on or after the international filing date
 "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
 "O" document referring to an oral disclosure, use, exhibition or other means
 "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

20 February 1997

Date of mailing of the international search report

28 -02- 1997

Name and mailing address of the ISA/
 Swedish Patent Office
 Box 5055, S-102 42 STOCKHOLM
 Facsimile No. +46 8 666 02 86

Authorized officer

Wiva Asplund
 Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE96/01459

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See extra sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE96/01459

An apparatus according to claim 1 with some of the characterizing features related to a certain embodiment according to figures 1-5, 8 and 9.

An apparatus according to independent claim 9 with some of the characterizing features differing from those in claim 1 and related to another embodiment according to figures 10a & b.

The method according to claim 12 comprises characterizing features related only to claim 1.

Further, dependent claim 4, referring to claim 2, which refers to claim 1, relates to figure 6, which is not consistent with the feature on lines 10-11 in claim 1.

Also, dependent claims 15 and 16, referring to the method in claim 12, which comprises characterizing features related only to the apparatus in claim 1, comprise features relating to figure 6, which is not consistent with claim 1, lines 10-11.

Claim 1 and claim 9 are each considered to define a single invention with no technical features of special character in common.

INTERNATIONAL SEARCH REPORT
Information on patent family members

03/02/97

International application No.

PCT/SE 96/01459

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A1- 9426403	24/11/94	AU-A- 6763294	12/12/94
		EP-A- 0725674	14/08/96
		SE-C- 500430	27/06/94
		SE-A- 9301599	27/06/94
WO-A1- 9322041	11/11/93	AU-A- 4274993	29/11/93
		EP-A- 0726805	21/08/96
		SE-B,C- 470303	17/01/94
		SE-A- 9201353	30/10/93

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.